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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,644	03/29/2004	Jill M. Cielo	PC-1485	7628

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
01/28/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/811,644	<b>Applicant(s)</b> CIELO, JILL M.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 4-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                     |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                         | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/29/2004</u> . | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

The prosecution of this application has been transferred from examiner Jyothsna Venkat to examiner Isis Ghali.

The receipt is acknowledged of applicant's IDS filed 03/29/2004; and election filed 10/31/2007.

#### ***Election/Restrictions***

1. Applicant's election with traverse of invention I, claims 1-3, 13, and 14 in the reply filed on 10/31/2007 is acknowledged. The traversal is on the ground(s) that the three inventions do not need separate search or separate examiners to examine them. This is not found persuasive because the composition of invention I not necessary produced by the method of invention II, and can be produced by forming two phases by mixing some of the ingredients together to form first phase and making a second phase by the rest of the ingredients and then mix the two phases together according to the process disclosed by Liu et al., US 5,976,555. Additionally, the composition of invention I can be used for purpose different than claimed by invention III such as simple cleansing and conditioning of hair. The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however they are extensive since the patent examiner searches the

databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present three distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 4-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions II and III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/31/2007.

Claims 1-3 and 13-14 are included in the prosecution.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 13 contain improper Markush format. Proper Markush format to be followed in the claim should have the expression

"selected from the group consisting of", and only the last two members of the Markush group are separated by the connector operator "and" OR "or". Claim 1 randomly contains the proposition "and" in parenthesis and such bracketed words render the claim indefinite because it is unclear whether the bracketed limitation(s) are part of the claimed invention. Furthermore, regarding the amounts recited by claims 1, it is not certain to which ingredient they correspond. Regarding claims 1 and 13, it is not certain if all the ingredients listed together in one group are required or only one of them is required. For example, are all of: "sodium laureth sulfate, disodium oleamide MEA sulfosuccinate, cocamide DEA, cocamidopropyl betaine" are required or only one of them? Claim 1 recites one range for all of them, and use bracketed "and" in between. The claims are therefore confusing. Additionally, claim 1 repeats some of the ingredients such as cocamidopropyl betaine and tetrasodium EDTA.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 2003/0007941 ('941), 2002/0119174 ('174), US 6,030,948 ('948), WO 96/25943 ('943) and US 6,376,557 ('557).

US '941 teaches composition for treating hair loss and useful for treating different types of alopecia, the composition comprising carrier comprising water; up to 11.5% of the composition ammonium lauryl sulfate; 2-4%, sodium laureth sulfate; 2% cocamide MEA; 0.1% sodium chloride; 1-3% cocamidopropyl betaine; 0.5% fragrance (example C, page 16). Additionally, the reference disclosed the topical composition may contain propylene glycol (paragraph 0280), and urea (paragraph 0294).

US '941 does not teach tall oil, EDTA, methyl paraben, propyl paraben, disodium salts of sulfosuccinate, cocoamide DEA, alkyloxypolyethyleneoxyethanol, and sodium sulfate as claimed by claims 1 and 13.

US '174 teaches composition for regulating hair growth comprising pine oil (tall oil), EDTA, methyl paraben, propyl paraben, coconut monethanolamide (cocamide MEA) and coconut diethanolamide (cocoamide DEA), lactamide monethanolamine, disodium salts of sulfosuccinate and sodium sulfate (paragraphs: 0036, 0084, 0102, 0103, 0112, 0133, 0141, 0234, 0304, 0331, 0336, 0351).

US '948 teaches hair regeneration composition useful for treating alopecia comprising urea gel and alkyloxypolyethyleneoxyethanol (abstract; col.2, lines 47-50; table 4 at col.11).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition to treat hair loss comprising water; ammonium lauryl sulfate; sodium laureth sulfate; cocamide MEA; sodium chloride; cocamidopropyl betaine; propylene glycol, and urea as disclosed by US '941, and add the ingredients disclosed by US '174 comprising pine oil, EDTA, methyl paraben, propyl

paraben, lactamide monethanolamine, disodium salts of sulfosuccinate, and sodium sulfate and further add alkyloxypolyethyleneoxyethanol disclosed by US '948 motivated by the teaching of US '174 and US '948 that composition comprising such ingredients are useful to regulate hair growth and treat alopecia, as desired by US '941, with reasonable expectation of having composition comprising all the above ingredients disclosed by the three references in one composition, wherein the composition effectively useful to treat hair loss and regeneration and regulate hair growth in person suffering from alopecia.

The combination of the references does not teach the exact amounts of some ingredients as instantly claimed. However, the claimed amounts do not impart patentability to the claims, absent evidence to the contrary.

The combination of US '941, US '174 and US '948 does not teach enzymes as claimed by claims 1-3, 13-14.

WO '943 teaches composition to stimulate hair follicles and hair growth, wherein the composition comprises enzymes trypsin (protease) and dispase (lipase) in effective amounts to enhance the penetration of the individual components in the hair growth composition through intact skin. The amount of enzymes is less than 1% (abstract; page 16, first two paragraphs).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hair growth generation composition comprising the ingredients disclosed by the combination of US '941, US '174 and US '948, and further add trypsin and dispase enzymes disclosed by WO '943 because WO '943 teaches

enzymes enhance the penetration of the individual components in the hair growth composition through intact skin, with reasonable expectation of having composition stimulating hair growth that comprises enzymes that effectively enhance the penetration of the individual components in the hair growth composition through intact skin to achieve enhanced successful hair growth stimulation.

Although the combination of US '941, US '174 and US '948 teaches composition comprising urea, however, the combination does not explicitly teach diazolidinyl urea as claimed by claims 1 and 13.

US '557 teaches hair growth promoter composition useful to treat alopecia and comprising diazolidinyl urea that has effective anti-bacterial and preservative action on the composition (abstract; col.8, lines 3-7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hair growth generation composition comprising the ingredients disclosed by the combination of US '941, US '174 and US '948, and further add diazolidinyl urea disclosed by US '557 because US '557 teaches diazolidinyl urea has effective anti-bacterial and preservative action on the hair growth promoter composition, with reasonable expectation of having composition to promote hair growth that comprises diazolidinyl urea that provides effective anti-bacterial and preservative action on the composition to achieve stable hair growth composition.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-



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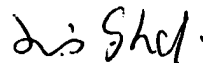
0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali  
Primary Examiner  
Art Unit 1611

IG



ISIS GHALI  
PRIMARY EXAMINER